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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,233	02/19/2004	Ross Jonathan Hamel	008932-0726-999	7395
51832	7590	02/12/2007		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/783,233	<b>Applicant(s)</b> HAMEL, ROSS JONATHAN	
	<b>Examiner</b> David Comstock	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 10-30, 40, 48-65, 78-80, 82 and 87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 31-39, 41-47, 66-77, 81 and 83-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 41-47, 72-77, 81 and 83-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Standerwick et al. (3,072,118).

Standerwick et al. disclose a fracture assembly comprising a reduction platform, e.g. 2, having receiving holes 28, a fragment manipulator, e.g. 8, having a bone engaging end 33, and a nut, e.g. 14, threadably and adjustably engaging the manipulator above the platform. The nut engages the top of the platform and the platform is between the nut and the bone engaging end of the manipulator. The second end of the manipulator includes a tool-engaging portion with a coupling surface 3. The bone engaging end has a self-drilling tip 33 (see col. 2, lines 48-51). The manipulator includes a second outer diameter portion 30 that is larger than a first outer diameter portion 32 and comprises a diameter that is smaller than a receiving hole. With regard to claim 72, the device is positioned over bone and the fragment manipulator is inserted through the reduction platform. (See, e.g., Fig. 1 and col. 3, line 14 - col. 4, line 27.) The fragment manipulator is inserted into bone. The nut is threaded onto the fragment manipulator and is made to contact the platform. The nut draws the manipulator

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upward. Claims 73-77, 81 and 83-86 have not been afforded patentable weight, since it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 31-34 and 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Standerwick et al. (3,072,118).

Standerwick et al. disclose the claimed invention except for explicitly disclosing that a self-drilling tip could comprise a tip with expanding and constant diameter threaded portions. However, such threaded tips and drill point tips are equivalent self-drilling structures known in the art. Therefore, it would have been obvious to a person of ordinary skill in the art to have substituted a threaded self-drilling tip for the drill point tip, since this merely involves the substitution of functionally equivalent structures known in the art. Likewise, it also would have been obvious to have substituted any number of common shapes for the reduction platform, including, for example, cylindrical, since this would amount to the substitution of functionally equivalent platform structures known in the art.

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Claims 8, 9 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Standerwick et al. (3,072,118) in view of Letendart et al. (6,432,109).

Letendart et al. disclose the claimed invention except for the nut comprising a spherical nose interface. Letendart et al. disclose a similar device having a nut 4 comprising a spherical nose interface 9 to allow the device to be easily adjusted in a desired direction and facilitate the procedure (see, e.g., Fig. 5 and col. 2, lines 1-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the assembly of Standerwick et al. with a nut comprising a spherical nose interface, in view of Letendart et al., in order to allow the device to be easily adjusted in a desired direction and facilitate the procedure.

Claims 35, 36, 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Standerwick et al. (3,072,118), as applied to claims 34 and 69 above, and further in view of Bittner, Jr. (2,055,024).

Standerwick et al., as modified, discloses the claimed invention except for the connection clamp and thumb wheel for the support system. Bittner, Jr. discloses a similar device comprising a connection clamp 6, 7, 8, 9 and a thumb wheel 5 for a support system to facilitate rapid adjustments and to promote proper healing (see, e.g., Fig. 1; col. 1, lines 15-17; and col. 4, lines 14 and 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the assembly of Standerwick, et al. with a connection clamp and thumb wheel for the support system, in view of Bittner, Jr., in order to facilitate rapid adjustments and to promote proper healing.

### ***Response to Arguments***

In response to applicant's continued argument that Standerwick does not disclose or render obvious the claimed invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Standerwick et al. discloses the claimed structure and is at least capable of performing the intended use as set forth in Applicant's claims. While Standerwick et al. disclose that the manipulators (pins) of the device may be located so as to avoid *interference* with damaged scalp or skull areas (see column 5, lines 46-48), this is not tantamount to a teaching away from a use of the device on any portion of the skull, whether damaged or not. In fact, the qualifier "*may*," makes clear that attachment of the device to damaged portions of the skull is *within* the scope of the disclosure. Moreover, Standerwick et al. also discloses that the scope of the invention goes beyond fixation and is adaptable to the solving of a large variety of problems encountered in face and neck injuries (col. 1, lines 50-52). In addition, the device is provided with a wide variety of adjustable positions (col. 1, lines 56-58). The method of using the device includes turning the nuts to loosely contact the platform and continuing to turn them to stabilize them on the manipulator in a properly adjusted position (col. 2, lines 25-28). Applicant argues that the reference "discloses nothing" about rotating any of the nuts to draw a manipulator upward. However, Standerwick et al. disclose that each manipulator is

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adjustably connected to the platform, such as by manually operable nuts..." (see col. 2, lines 25-28). Thus, when a manipulator is engaged in bone and a top nut is turned, the manipulator is urged upward together with the bone attached thereto. The other nut would not be tightened for stabilization purposes until proper adjustment has been achieved (*id.* and see col. 3, lines 14-33). It is also noted that since Applicant uses the open transition "comprising," having a second nut in addition to a first nut does not present a problem, especially in view of how the device is used. Finally, and with respect to the method claims, it is noted that "reduction" is only mentioned in the preamble and not in any positive steps of the method.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



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SUPERVISORY PATENT EXAMINER